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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/117,447 12/02/98 LUBITZ W , P564-8013

HM22/1222
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EXAMINER

MINNIFIELD, N

ART UNIT	PAPER NUMBER
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1645

12

DATE MAILED:

12/22/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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Office Action Summary

Application No.

09/117,447

Applicant(s)

LUBITZ ET AL

Examiner

N. M. Minnifield

Group Art Unit

1645



☒ Responsive to communication(s) filed on Oct 2, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-17, 19-24, 26, 28-30, 32-34, and 37-57 is/are pending in the application

Of the above, claim(s) 21-24, 26, 28-30, 32-34, 37-45, and 48-57 is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-17, 19, 20, 46, and 47 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☒ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892 (2 sheets)

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 7/31/98

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

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— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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DETAILED ACTION

1. Applicant's election without traverse of Group I and Species I (SbsA-S layer protein SEQ ID NO:1), claims 1-17, 19, 20, 46 and 47, in Paper Nos. 8 (filed 5/26/00) and 11 (filed 10/02/00) is acknowledged. Claims 1-17, 19, 20, 46 and 47 are under examination in the pending application.
2. Claims 21-24, 26, 28-30, 32-34, 37-45, and 48-57 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions or species, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 8 and 11.
3. Claims 19 and 20 are objected to because of the following informalities: these claims depend from canceled claim 18. Appropriate correction is required.
4. Claims 1-17, 19, 20 46 and 47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 and those depending claims are vague and indefinite because it contains the use of an alternative expression wherein the limitation covers two different elements, i.e. the elements in "(I)" are not the same as the elements in "(ii)". See ^{MPA} ~~MAEP~~ 706.03(d), paragraph 5. Claim 14 and those depending claims are vague and

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indefinite because it contains the use of an alternative expression wherein the limitation covers two different elements, i.e. the elements in "(a)" are not the same as the elements in "(b)" and the elements in "(a)" are not the same as the elements in "(c)". See ~~MEP~~^{MPEP} 706.03(d), paragraph 5. Claim 15 and those depending claims are vague and indefinite because it contains the use of an alternative expression wherein the limitation covers two different elements, i.e. the elements in "(I)" are not the same as the elements in "(ii)". See ~~MEP~~^{MPEP} 706.03(d), paragraph 5. Claim 16 and those depending claims are vague and indefinite because it contains the use of an alternative expression wherein the limitation covers two different elements, i.e. position "2504" is not the same as position "2649". See ~~MEP~~^{MPEP} 706.03(d), paragraph 5. Claims 4-7 are vague and indefinite in the recitation of "several"; what are the metes and bounds of "several"? Regarding claims 8-10 and those depending claims, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See ~~MEP~~^{MPEP}.

§ 2173.05(d). Claims 7 and 19 are vague and indefinite in the recitation of "in particular". Claim 1 recites the limitation "polypeptide" in lines 21 and 22. There is insufficient antecedent basis for this limitation in the claim; elsewhere in the claims the term "protein" is used. Claim 15 recites the limitation "polypeptide" in line 16. There is insufficient antecedent basis for this limitation in the claim; elsewhere in the claims the term "protein" is used. Claims 1, 15, 16 and those claims depending from 1, 15, and 16 are vague and indefinite in the recitation of

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"stringent conditions". The specific conditions are not set forth in the claims, neither is a specific method set forth in the specification. Possibilities for hybridization are determined by the stringency of the procedure. Stringency, determined by the physical and chemical conditions, established the degree of hybridization. Without a clear definition as to the metes and bounds of the chemical conditions employed during the hybridization one of skill in the art would be unable to practice the broadly claimed invention. Claim 1 is vague and indefinite in that it is not clear whether this method is intended to produce the S layer protein only or a method to produce the fusion protein which comprises the S layer protein and a heterologous protein; it appears that Applicants may intend this since claim 1, line 21 and 22 refer to polypeptides. If this is what Applicants intend then claim 4 is a duplicate of claim 1. Does claim 4 mean that claim is a process of producing a pure S-layer protein or a fusion/heterologous protein of S-layer protein and some other protein (i.e. the insertion)? Clarification is requested.

It is requested that Applicants review all pending claims with regard to claim language to insure that the claims read as clearly and be as definite as possible, as well as follow US claim language practice.

5. The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an enabling disclosure for the claimed invention. It is apparent that *E. coli* strain POP2135 is required to practice the claimed invention. As a

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required element it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. § 112, first paragraph, may be satisfied by a deposit of the above mentioned strains and plasmids. See 37 C.F.R. 1.802.

The specification does not provide a repeatable method for obtaining the strains and it does not appear to be readily available material. Deposit of strains would satisfy the enablement requirements of 35 U.S.C. § 112. If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 C.F.R. 1.808.

If the deposits have not been made under the provisions of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository and that the following criteria have been met:

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(a) during the pendency of the application, access to the deposits will be afforded to one determined by the Commissioner to be entitled thereto;

(b) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent;

© the deposits will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;

(d) a viability statement in accordance with the provisions of 37 CFR 1.807; and

(e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition, the identifying information set forth in 37 CFR 1.809(d) should be added to the specification. See 37 CAR 1.803 - 37 CFR 1.809 for additional explanation of these requirements.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was

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made in order for the examiner to consider the applicability of 35 U.S.C. 103[©] and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1-3, 15-17, 19, 20, 46 and 47 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuen et al (*Gene*, 1994).

The claims are directed to a nucleic acid sequence, cells, vectors, and a process of producing S-layer proteins.

Kuen et al disclose that the S-layer protein was cloned and expressed in a prokaryotic cell system and discloses the nucleic acid sequence of the S-layer protein (abstract; p. 116, col. 1). The prior art discloses cells for transformation and a vector (p. 116, Experimental and Discussion). Kuen et al disclose the nucleotide sequence including signal sequence of the *sbs* gene which encodes the S-layer protein (p. 117, col. 2; figure 2; table 1; p. 119, col. 2). Kuen et al anticipates the claimed invention.

11. Claims 1-17, 19, 20, 46 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuen et al (*Gene*, 1994) taken with Deblaere et al (WO9519371).

The claims are directed to a nucleic acid sequence, cells, vectors, and processes of producing S-layer proteins or S-layer proteins with an insertion (enzymes, antigens, immunogens, etc).

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Kuen et al teach that the S-layer protein was cloned and expressed in a prokaryotic cell system and teach the nucleic acid sequence of the S-layer protein (abstract; p. 116, col. 1). The prior art teaches cells for transformation and a vector (p. 116, Experimental and Discussion). Kuen et al teach the nucleotide sequence including signal sequence of the *sbs* gene which encodes the S-layer protein (p. 117, col. 2; figure 2; table 1; p. 119, col. 2). Kuen et al teach the claimed invention except for the concept of insertion of heterologous proteins/polypeptides.

However, Deblaere et al teach a host cell which is provided with an S-layer comprising a fusion polypeptide consisting essentially of the S-layer protein and a heterologous polypeptide (abstract; p. 6; claims). Deblaere et al teach that the gene for the S-layer protein includes strong promoter sequences, signal peptide coding sequences as well as a transcription termination sequence (p. 2). The prior art teaches recombinant DNA molecules that includes a SLP system capable of expressing and presenting a fusion polypeptide in a wide variety of bacteria (p. 5). Deblaere et al teach that the insertion or heterologous protein can be a physiologically active polypeptide such as an enzyme, a polypeptide drug or a cytokine (interferon), foreign epitope or polypeptide immunogen, etc (p. 9). The immunogen can be an antigen of a pathogen such as a virus, bacterium, fungus, yeast or parasite (pp. 9-10). Further, the prior art teaches expression vectors and suitable host cells as well as methods of producing the proteins (p. 10-12). It

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would have been obvious to a person of ordinary skill in the art at the time the invention was made to use the methods/processes as taught by both Kuen et al and Deblaere et al with the reasonable expectation of success of obtaining a process to produce pure S-layer protein, a recombinant S-layer protein or a fusion protein comprising the S-layer protein having an insertion of a heterologous polypeptide as presently claimed. Kuen et al sets forth nucleotide sequence of the S-layer protein while both references provide the process methods, cells, and vectors. Deblaere et al provides the motivation and suggestion to insert foreign or heterologous protein (DNA) into the DNA of the S-layer for the purpose of making fusion proteins that are expressed. It is noted that the prior art does not specifically teach the insertion at the specific positions that are set forth in claim 16; however it would have been obvious to a person of ordinary skill in the art at the time the invention was made to insert the foreign DNA at any cleavage site that would still allow for the assembly of the S-layer protein. The claimed invention is prima facie obvious in view of the teachings of Kuen et al taken with Deblaere et al, absent any convincing evidence to the contrary.

12. No claims are allowed.

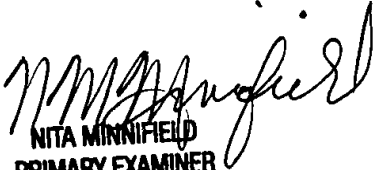
13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

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14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is (703) 305-3394. The examiner can normally be reached on Monday-Thursday from 7:00 AM-4:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R. F. Smith, can be reached on (703) 308-3909. The fax phone number for Technology Center 1600 is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.


NITA MINNIFIELD
PRIMARY EXAMINER

N. M. Minnifield

December 13, 2000